

Remarks

Status of the Claims

Claims 12, 30-32, 35, 39, 61, 64, 68-69, 71, 72, 74-78, 80 and 102-114 were rejected in the January 31, 2008 Office Action. New claims 115-122 are added by the present amendment. Upon entry of the present amendments, claims 12, 30-32, 35, 39, 61, 64, 68-69, 71-72, 74-78, 80, and 102-120 will be pending in this application. Claims 30, 61 and 115 are the independent claims that are pending in the present application.

New claims 115-120 are supported throughout the specification, for example, at page 15, lines 8-11 and Figs. 3 and 16. New claims 121-122 are supported throughout the specification, for example, at page 9, lines 3-7 and page 18, lines 10-15 and 28-31.

The Claims Are Not Obvious Based On EP 0517030 (Siebels) and U.S. Pat. 5,989,289 (Coates)

Claims 12, 30-32, 107-109 and 111-112 were rejected under 35 U.S.C. § 103(a) for obviousness based on EP 0517030 (Siebels) in view of U.S. Pat. No. 5,989,289 (Coates). Applicants respectfully disagree with the Patent Office's rejection for at least two reasons: (1) neither reference discloses a demineralized segment of allograft bone that has a hole drilled therein, and (2) one of ordinary skill in the art would not have combined the teachings of Siebels and Coates as indicated by the Office Action because there would have been no reasonable expectation of success.

1. The Cited References Do Not Disclose All The Claim Elements

Applicants submit that neither Siebels nor Coates discloses or suggests an assembled graft implant where a demineralized segment of allograft bone is fastened together with a mineralized segment of allograft cortical bone. Also neither reference teaches or suggests an assembled bone implant where a demineralized segment has a hole drilled therein for receiving and frictionally engaging said at least one pin.

Siebels teaches that disks and/or pins are made from fiber-reinforced plastic and carbon-fiber reinforced plastic. Nowhere does Siebels disclose or suggest use of any

bone material. The Office Action acknowledges this: "However, Siebels fails to disclose making the implant pieces of cortical bone ..." (Office Action, page 3). The Office Action contends that Coates discloses a demineralized segment of allograft bone because it states that its spacers can have osteogenic material of demineralized bone and/or allograft bone applied to them. (Office Action, page 5).

Coates does not disclose or suggest a demineralized bone segment fastened together with a mineralized bone segment by at least one pin, nor a demineralized segment having a hole drilled therein for receiving and frictionally engaging the pin. Coates only discloses an osteogenic material that can be packed in a chamber or impregnated with a solution, and that is not a disclosure of a demineralized segment of allograft bone.

An osteogenic material can be applied to the spacers of this invention by **packing the chamber** 130 with an osteogenic material 148 as shown in FIG. 4, by **impregnating the graft** with a solution including an osteogenic composition or by both methods combined. ... Any suitable osteogenic material or composition is contemplated, including autograft, allograft, xenograft, **demineralized bone**, synthetic and natural bone graft substitutes, such as bioceramics and polymers, and osteoinductive factors.

(Coates, Col. 6, lines 23-38)(emphasis added). Thus, when discussing the inclusion of demineralized bone, Coates discloses a packable material, such as a flowable paste, not a demineralized bone segment that is fastened together with a mineralized bone segment by at least one pin. Coates also does not teach or suggest a hole drilled in a demineralized segment for receiving and frictionally engaging a pin. In fact, it is unlikely that an osteogenic material packed into a chamber (such as a sponge or foldable strips or sheets) or impregnated into a graft (such as by applying a liquid osteogenic material to the graft) as discussed in Coates (see col. 7, lines 44-47 and col. 8, lines 8-18) would be effective in frictionally engaging a pin.

The present specification indicates that a bone segment is a single discrete piece rather than a packable material:

Specific embodiments of assembled implants have a combination of demineralized and mineralized regions, present or assembled into a **single, discrete piece (i.e., a segment)**, are shown to possess superior properties.

(page 10, lines 2-4 (emphasis added)). Thus, Coates does not disclose a demineralized segment of allograft bone where it discusses a packable material or a solution for impregnating a spacer.

The Office Action draws the conclusion that “all the pieces could be called a mineralized segment or a demineralized segment since each piece would contain at some of each material.” (Office Action, page 5). Applicants submit that this is not a reasonable construction of these terms. To clarify this point, Applicants note that a mineralized bone spacer as in Coates having a coating of osteogenic material would more properly be termed a mineralized segment having a demineralized portion. This is consistent with the language of claim 31, which is being amended to clarify that the demineralized segment of allograft bone comprises a region of mineralized bone.

2. No Reasonable Expectation of Success

The January 31, 2008 Office Action contended that a person skilled in the art would have modified the implant of Siebels by replacing the fiber-reinforced plastic used to make Siebels’ implants with cortical bone as disclosed in Coates. Applicants submit that there would not be a reasonable expectation of success that cortical bone could take the place of Siebels’ fiber-reinforced plastic in view of Siebels’ objectives.

Siebels emphasizes the importance of the particular fiber-reinforced plastic material used to make its implant. (See, for example, pages 3-4, 6-8, 10-11, and 13-14, and Figs. 5-8). No other material is identified by Siebel for making its implants. Nonetheless, the Office Action finds that one skilled in the art would switch Siebels’s material from fiber-reinforced plastic to cortical bone. This changes a fundamental idea and purpose of the Siebels reference.

Siebels teaches that disks and/or anchoring pins are made from "fiber reinforced plastic" and "carbon-fiber reinforced plastic." Specifically, on page 3, the Siebels reference states, "The disk-shaped implant is preferably made of fiber-reinforced plastic," and on page 6, the Siebels reference states that "the disks are made of a carbon-fiber reinforced plastic (CFP) whereby the anchoring means – according to the design of the implant – can consist of the same, or another material." *Id.* at pp. 3, 6. Siebels illustrates the manufacture of its fiber-reinforced plastic in Figures 5 and 6.

This choice of material is important to Siebels' objectives and to Siebels' view as to what constitutes his invention. Siebels repeatedly emphasizes the objectives of ease of manufacturing and the ability to rapidly implant in a patient. (page 2). The Siebels reference describes how to produce a single-piece implant, in accordance with a preferred embodiment of the invention, by cutting a disk out of a prefabricated solid or hollow strand. The hollow strand consists of "a multiple number of braiding layers [plaiting layers]." (pages 3-4). The braiding layers are "wound up one after another" on a mandrel. The fibers are impregnated with a matrix, and the matrix is solidified. (page 11). Then the disks are cut off at desired heights. Siebels states that these implants "can be manufactured in an extraordinarily easy way in which the fiber orientation equally imparts an optimal rigidity and strength to the implant." (page 4.) Siebels' easy manufacturing techniques are done by winding or pulling of fibers and then sawing or cutting disks from a longer tube. (pages 3-4 and 10-11). The manufacturing methods by which the implants of Siebels can "easily be manufactured" in accordance with the "basis of the [proposed] invention" make it evident that the fiber-reinforced plastics are important in Siebels. Siebels explains in great detail how the reinforcing fibers are to be wound. *Id.*

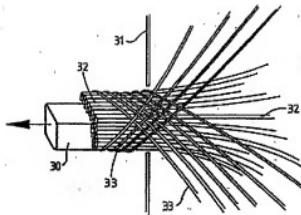


Fig. 5

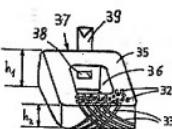


Fig. 6

Since Siebels relies so heavily on the use of particular materials and manufacturing techniques to achieve its objectives, one would not expect that a completely different material could be substituted and still meet the same objectives. “If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” MPEP §2143.01, page 2100-141 (Rev. 6, Sept. 2007). One would not have expected that cortical bone could be used in place of the disks prepared from a multiple number of braided layers, or that the easy manufacturing techniques would still be useful.

For at least these reasons, the subject matter of claims 12, 30-32, 107-109 and 111-112 would not have been obvious based on the Siebels and Coates references.

**The Claims Would Not Have Been Obvious
Based On Siebels and Coates In View of Bonutti**

Claims 35, 39, 61, 64, 68, 69, 71, 72, 74-78, 80, 102-106, 110, 113 and 114 were rejected under 35 U.S.C. § 103(a) for obviousness based on Siebels and Coates and further in view of U.S. Patent No. 5,545,222 (Bonutti). Claim 61 is an independent claim, and the other claims are dependent upon claim 61.

Claim 61 recites an assembled implantable bone graft suitable for use in humans. The graft comprises a first machined segment of allograft bone pinned with at least one pin to a second machined segment of allograft bone. The graft also comprises a soft tissue affixed between said first segment and said second segment. Applicants submit that the combination of Siebels, Coates and Bonutti do not render claim 61 unpatentable because none of those three references discloses or suggests a soft tissue affixed between a first bone segment and a second bone segment.

The Office Action fails to provide any reason or rationale as to why it would have been obvious to fix a soft piece of tissue somewhere between the bone pieces in the Siebels implant as modified by Coates. For starters, where would the soft tissue be placed? What is the purpose of adding soft tissue to the Siebels implant? None of the cited references provide or suggest answers to these questions. The Siebels and Coates references relate to

invertebral spacers to be inserted between vertebrae in a spinal column. Neither Siebels nor Coates discloses any reason to insert a soft tissue into an intervertebral implant. Siebels indicates that rigidity (not flexibility) is desirable in intervertebral spacers. (See, for example, page 4).

Moreover, the cited references do not disclose or suggest a soft tissue affixed between first and second segments of allograft bone that are pinned. Bonutti discloses the use of a tissue press to make a composite graft, and teaches that bone tissue can be compressed around the ends of a tendon tissue. (col. 3, lines 24-31). Bonutti states that its tissue press can be used to compress bone fragments into one larger piece (col. 10, lines 56-60). For the purpose of holding compressed material together, Bonutti discloses the inclusion of fibrin, a blood clotting component, as an adhesive so there would be no reason to use pins to hold bone fragments together from Bonutti's perspective. Indeed, the bone pins would be at risk of being crushed in Bonutti's tissue press.

For at least these reasons, the subject matter of claims 12, 30-32, 35, 39, 61, 64, 68-69, 71-72, 74-78, 80, 102-106, 110, 113 and 114 would not have been obvious to a person skilled in the art at the time that the Applicants' invention was made.

New Claims 115-120

New claims 115 to 120 recite an assembled graft implant comprising three individual machined segments fastened together with at least one pin machined from cortical bone. One of the machined segments is a demineralized segment of allograft bone, and the other two machined segments are mineralized segments of allograft cortical bone. Each of the machined segments has a hole drilled therein for receiving and frictionally engaging said at least one pin.

None of the cited references discloses an assembled implant comprising three individual machined segments where one of the machined segments is a demineralized segment of allograft bone, or where each of the three machined segments has a hole drilled therein.

New Claims 121 and 122

New claim 121 depends from claim 30 and recites an assembled graft implant wherein at least one demineralized segment is a machined segment of allograft bone. The Coates reference does not disclose a demineralized segment that is a machined segment of allograft bone. As discussed above, Coates discloses a packable material, such as a flowable paste, not a demineralized bone segment that is fastened together with a mineralized bone segment by at least one pin.

New claim 122 depends from claim 61 and recites an assembled graft implant wherein the soft tissue is affixed via pinning between said first segment and said second segment, and the soft tissue is sandwiched between said first and second machined segments of allograft bone. The Bonutti reference does not disclose such an implant.

Copending Applications

The Office Action requests that Applicants provide a list of “all copending applications that set forth similar subject matter to the pending claims.” Applicants do not understand what the Examiner considers “similar,” and request clarification.

The present application claims priority from Application No. 09/782,594 (U.S. Publication No. 20010031254), and from Application No. 09/905,683 (U.S. Publication No. 20020138143). Application No. 10/387,322 (U.S. Publication No. 20040115172) claims priority from the present application.

Additionally, in a good faith effort to facilitate examination and to comply with the Examiner’s request, Applicants also provide the following list of copending applications that may be of interest to the Examiner.

Application No. 11/007,525 (U.S. Publication No. 20050101957)

Application No. 11/007,679 (U.S. Publication No. 20050119744)

Application No. 11/073,400 (U.S. Publication No. 20060200236)

Application No. 11/073,202 (U.S. Publication No. 20060212036)

Application No. 11/073,281 (U.S. Publication No. 20060200235)

Application No. 11/313,280 (U.S. Publication No. 20060229722)

Application No. 29/255,380 (unpublished)

Application No. 29/255,376 (unpublished)

Application No. 29/255,371 (unpublished)

Application No. 29/255,378 (unpublished)

Application No. 29/255,379 (unpublished)

Application No. 11/674,084 (unpublished)

Copies of the unpublished applications will be separately provided under MPEP §724 in a sealed envelope.

The disclosure of the foregoing applications shall not be considered a representation that the subject matter of these applications is similar or material to the present application.

Statement Regarding Previous Responses

In the present application, Applicants have submitted several previous responses discussing the Siebels and Coates references. The Examiner has (thus far) maintained that the pending claims are not patentable over those references and has not found Applicant's responses and arguments fully persuasive. Accordingly, Applicants hereby rescind any disclaimer of claim scope made in any responses prior to the present paper. The Examiner is advised that any previous disclaimer, if any, and the prior art that it was made to avoid, may need to be revisited. Nor should a disclaimer, if any, in the present application be read back into any predecessor or related application.

Petition for a One Month Extension of Time

Applicants hereby petition for a one-month extension of time in which to respond to the Office Action of January 31, 2008. The Commissioner is authorized to

charge the requisite extension fee of \$120.00, and any necessary fees for this submission, to the Deposit Account of McAndrews, Held & Malloy, Account No. 13-0017.

Conclusion

In view of the amendments and arguments provided herein, Applicants believe that all bases for rejecting claims 12, 30-32, 35, 39, 61, 64, 68-69, 71-72, 74-78 and 80 have been overcome. Applicants respectfully submit that claims 12, 30-32, 35, 39, 61, 64, 68-69, 71-72, 74-78, 80 and 102-106 of the instant application are in a condition for allowance. The Examiner is invited to telephone the applicants' undersigned attorney at (312) 775-8202, if any unresolved matters remain.

The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Account No. 13-0017, in the name of McAndrews, Held & Malloy, Ltd.

Respectfully submitted,

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